Nelson, Bettie L

From: Aimee Devor [adevor@clinimetrics.com]
Sent: Monday, December 09, 2002 2:07 PM
To: Bettie.L.Nelson@pmusa.com
Cc: Martin.Unverdorben@pmusa.com
Subject: RE: MONITORING OF ACCORD JLI-LONG TERM

Hi Bettie,

I apologize for the delay in getting this information to you. I was unexpectedly out of the office on Friday.

Bob reviewed the procedures in place for handling data at MDS in Phoenix. The SOPs state that the information is to be recorded on a raw data sheet. Then per routine, the raw data sheets are put into a raw data file. The raw data files are picked up daily by Quality Control.

In this particular case, two Associates were responsible for raw data entry. One is no longer with MDS Pharma and the other does not clearly remember from that far back. There was some suggestion at the site that this procedure may have been complicated by the office move.

Bob questioned the site if QC makes a list of what is being retrieved from raw data file on a daily basis. William Baumgarter is not sure that this is done but is checking into the procedures QC has in place. Bob suggested to William that this be implemented to document procedures are being followed and minimize the loss of data in the future.

Bob will document his findings in his report of the visit.

Please let me know if you have any questions.

Kind regards,
Aimee

-----Original Message-----
From: Bettie.L.Nelson@pmusa.com [mailto:Bettie.L.Nelson@pmusa.com]
Sent: Wednesday, December 04, 2002 2:47 PM
To: adevor@clinimetrics.com
Cc: Martin.Unverdorben@pmusa.com
Subject: MONITORING OF ACCORD JLI-LONG TERM

Aimee,

Thanks for your return phone call. As I indicated, the Phoenix site is unable to locate urinary volume data for one of the baseline days for the
first group of subjects. Since Bob is there today and tomorrow, we'd like to
make certain that Bob Starr monitors the procedures that are in place for
handling laboratory data to determine what may have happened. I realize that
the office location changed, perhaps during this time and that may have contributed to the problem.

With best regards,
Bettie

(804) 274-1502
(804) 334-5923 (Cellular)
(804) 274-3982 (Fax)

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Nelson, Bettie L

From: Aimee Devor [adevor@clinimetrics.com]
Sent: Wednesday, December 04, 2002 11:03 PM
To: Bettie.L.Nelson@pmusa.com
Subject: RE: MONITORING OF ACCORD JLI-LONG TERM

Hi Bettie,

Thanks for your email. I have relayed this request to Bob. He will look into the situation and provide an update to me. I requested this be done as soon as possible after leaving the site.

Please let me know if there is anything else we can do for you.

Kind regards,
Aimee

-----Original Message-----
From: Bettie.L.Nelson@pmusa.com [mailto:Bettie.L.Nelson@pmusa.com]
Sent: Wednesday, December 04, 2002 2:47 PM
To: adevor@clinimetrics.com
Cc: Martin.Unverdorben@pmusa.com
Subject: MONITORING OF ACCORD JLI-LONG TERM

Aimee,

Thanks for your return phone call. As I indicated, the Phoenix site is unable to locate urinary volume data for one of the baseline days for the first group of subjects. Since Bob is there today and tomorrow, we'd like to make certain that Bob Starr monitors the procedures that are in place for handling laboratory data to determine what may have happened. I realize that the office location changed, perhaps during this time and that may have contributed to the problem.

With best regards,
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